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Proposed Maximum Residue Limit

PMRL2007-15

Spiromesifen

(publié aussi en français)

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Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the Pest Control Products Act (PCPA), has granted conditional registration to technical grade spiromesifen and the end-use product Forbid 240 SC Insecticide/Miticide for use in Canada to control whiteflies and mites on greenhouse vegetables (cucumbers, peppers and tomatoes), field corn, strawberries, tuberous and corm vegetables (Crop Subgroup 1C), leafy green vegetables (Crop Subgroup 4A), Brassica leafy vegetables (Crop Group 5), fruiting vegetables (Crop Group 8) and cucurbit vegetables (Crop Group 9). See Appendix I for a list of crop group commodities. The specific uses that were approved in Canada are detailed on the Forbid 240 SC Insecticide/ Miticide label (PCPA Registration Number 28590).

The evaluation of these spiromesifen applications indicated that the end-use product has merit and value and that the human health and environmental risks associated with the new uses are acceptable. Details on these registrations can be found in Evaluation Report ERC2007-08, *Spiromesifen*.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not pose an unacceptable health risk. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Currently, MRLs are legally established under the Food and Drug Regulations (FDR) after consultation through the Canada Gazette. Amendments to the *Food and Drugs Act (FDA)*, via Bill C-28, anticipated to come into force in 2008, will allow pesticide MRLs to be legally established under the PCPA without having to adopt MRLs by regulation under the FDA, resulting in a more efficient means of establishing, revising and revoking pesticide MRLs.

Consultation on the proposed MRLs for spiromesifen is being conducted via this document (see Next Steps). This action is being taken in advance of Bill C-28 coming into force to allow the MRLs to be legally established as soon as possible after the FDA is amended.

The proposed MRLs for spiromesifen in Canada in or on food are as follows:

Table 1 Proposed Maximum Residue Limits for Spiromesifen

Common Chemical Name	Chemical Name of Substance	MRL (ppm)	Foods
Spiromesifen	2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate, including the metabolite 4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one	12	Leafy greens (Crop Subgroup 4A), leafy Brassica greens (Crop Subgroup 5B)
		2.0	Head and stem Brassica vegetables (Crop Subgroup 5A), strawberries
		0.6	Cherry tomatoes, tomato paste
		0.45	Fruiting vegetables (Crop Group 8), except cherry tomatoes
		0.2	Cucumbers
		0.1	Cucurbit vegetables (Crop Group 9), except cucumbers
	2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate, including the metabolites 4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one and 4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]-1-oxaspiro[4.4]non-3-en-2-one	0.02	Field corn, tuberous and corm vegetables (Crop Group 1C)
		0.1	Milk fat
		0.05	Fat and meat byproducts of cattle, goats, horses and sheep
		0.03	Barley, sugar beet roots, wheat
Spiromesifen	2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate, including the metabolites 4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one and 4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]-1-oxaspiro[4.4]non-3-en-2-one	0.01	Meat of cattle, goats, horses and sheep
		0.005	Milk

A complete list of all MRLs established in Canada can be found in Table II, Division 15 of the FDR. Once the amendments to the FDA via Bill C-28 are in force, the list of legally established Canadian MRLs will be available on the PMRA's MRL webpage, which will be updated to include the MRLs listed in this document.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. For animal commodities, differences in MRLs can also be due to different livestock feed items and practices.

Table 2 identifies differences among MRLs in Canada, tolerances in the United States and Codex¹ MRLs. For the most part, the proposed MRLs in Canada are the same as corresponding tolerances established in the United States (listed in 40 CFR 180 by pesticide). However, Canadian MRLs are higher for two commodities and the United States does not have tolerances established for livestock meat commodities. Currently, there are no Codex MRLs established for spiromesifen (Codex MRLs searchable by pesticide or commodity).

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodities	Canadian MRLs (ppm)	American Tolerances (ppm)	Codex MRLs (ppm)
Cucurbit vegetables (Crop Group 9), except cucumbers	0.1	0.1	No Codex MRLs have been established for spiromesifen.
Cucumbers	0.2	0.1*	
Fruiting vegetables (Crop Group 8), except cherry tomatoes	0.45	0.45	
Cherry tomatoes	0.6	0.45*	
Meat of cattle	0.01	No US tolerance established.	
Meat of goats	0.01	No US tolerance established.	
Meat of horses	0.01	No US tolerance established.	
Meat of sheep	0.01	No US tolerance established.	
Milk	0.005	No US tolerance established.	

* Cucumbers and cherry tomatoes are not excepted from their crop groups in the United States and are therefore covered by the corresponding crop group tolerance.

¹ Codex is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for spiromesifen up to 75 days from the date of publication of this document. Please forward your comments to Publications (see contact information on the cover page of this document). Health Canada will consider all comments received before making a final decision on the proposed MRLs for spiromesifen and before posting an Established Maximum Residue Limit (MRL) document on the PMRA's website once the amendments to the FDA are in force.

Appendix I Crop Groups: Numbers and Definitions

Crop Group Number	Name of the Crop Group	Commodities Included
1C	Root and tuber vegetables, Tuberous and corm vegetables subgroup	Arracacha Arrowroot Cassava roots Chayote roots Chinese artichokes Chufa Edible canna Ginger roots Jerusalem artichokes Lerens Potatoes Sweet potato roots Tanier corms Taro corms True yam tubers Turmeric roots Yam bean roots
4A	Leafy vegetables except Brassica, Leafy greens subgroup	Amaranth Arugula Corn salad Dandelion leaves Dock Edible leaved chrysanthemum Endives Fresh chervil leaves Garden cress Garden purslane Garland chrysanthemum Head lettuce Leaf lettuce New Zealand spinach Orach leaves Parsley leaves Radicchio Spinach Upland cress Vine spinach Winter purslane

Crop Group Number	Name of the Crop Group	Commodities Included
5A	Brassica (cole) leafy vegetables, Head and stem Brassica subgroup	Broccoli Brussels sprouts Cabbage Cauliflower Chinese broccoli Chinese mustard cabbage Kohlrabi Napa Chinese cabbage
5B	Brassica (cole) leafy vegetables, Leafy Brassica greens subgroup	Bok choy Chinese cabbage Broccoli raab Collards Kale Mustard greens Mustard spinach Rape greens
8	Fruiting vegetables	Bell peppers Eggplants Groundcherries Non-bell peppers Pepinos Pepper hybrids Tomatillos Tomatoes
9	Cucurbit vegetables	Balsam apples Balsam pears Cantaloupes Chayote (fruit) Chinese cucumbers Chinese waxgourds Citron melons Cucumbers Edible gourds (other than those listed in this item) Muskmelons (other than those listed in this item) Pumpkins Summer squash Watermelons West Indian gherkins Winter squash